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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,799	08/06/2007	Rong Fan	DEX0499US.NP	2565

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LICATA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
05/06/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	10/593,799	FAN ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,5,6,8,11,13,15-17,21,22,24,26-28,30,34-40,43,44,48-52,56,58,62,67,68 and 71.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,2,5,6,8,11,13,15-17,21,22,24,26-28,30,34-40,43,44,48-52,56,58,62,67,68 and 71.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is an antibody produced by hybridoma of ATCC accession no. PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629, or which competes for binding the same epitope as the epitope bound by the antibody produced by hybridoma of ATCC accession no. PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629. In view of this Keolsch et al (WO 98/22597, 5/28/1998, IDS filed 12/7/2006) reads on the claim. Keolsch et al teach antibodies that bind napsin A, which as evidenced by the specification at page 11, lines 23-24 is identical to Lng105. Therefore, it is the examiner's position that the antibodies of Keolsch et al would compete for the same epitopes recognized by the antibodies having ATCC accession numbers PTA-5878, PTA-5879, PTA-6146, PTA-6147 and PTA-6629. One of ordinary skill in the art would reasonably conclude that Keolsch et al antibodies also possesses the same structural and functional properties as those of the antibodies claimed and, therefore, it appears that Keolsch et al have produced antibodies that are identical to the claimed antibodies. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibodies with the antibodies of Keolsch et al, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed antibodies and the antibodies of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2, 5-6, 8, 11, 13, 15-17, 21-22, 27-28, 30 and 50-51, drawn to an antibody produced by the hybridoma PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629, or an antibody that competes with said antibodies for binding to Lng105 and pharmaceutical compositions comprising such.

Group II, claims 24 and 26, drawn to host cells encoding an antibody produced by the hybridoma PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629, or an antibody that competes with said antibodies for binding to Lng105, and a method for producing the antibody comprising culturing the cells.

Group III, claims 34-36, 39-40, 43-44 and 48-49, drawn to a method of treating Lng105 expressing cancer cells in a patient comprising administering an antibody produced by the hybridoma PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629, or an antibody that competes with said antibodies for binding to Lng105.

Group IV, claims 52, 56, 58, 62 and 67-68, drawn to a method of detecting cells expressing Lng105 in a sample comprising contacting the sample with an antibody produced by the hybridoma PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629, or an antibody that competes with said antibodies for binding to Lng105, determining the level of binding or internalization of the antibody wherein binding or internalization of the antibody indicate expression of Lng105.

Group V, claim 71, drawn to a screening method for antibodies that bind to an epitope bound by an antibody produced by the hybridoma PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629 comprising combining a Lng105-containing sample with a test antibody and an antibody produced by the hybridoma PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629, determining the level of antibody binding and comparing the level to a control mixture, wherein the level of antibody binding of the antibody produced by the hybridoma PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629 to Lng105 in the mixture as compared to the control is

indicative of the test antibody's binding to the same epitope that is bound by the antibody produced by the hybridoma PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teachings of Keolsch et al the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Inventions of Groups I-II represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The antibody of Group I and the host cells of Group II are structurally and chemically different from each other. The antibody is raised by immunization while the host cells are made by transformation/transfection. Furthermore, the host cells can be used to produce materially different proteins and the antibody can be used to immunopurify the antigen, for example. The examination of each group would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions I-II are patentably distinct.

The methods of Inventions of Groups III-V differ in the method objectives, method steps and parameters and in the reagents used. The invention of Group III recites a method of treating Lng105 expressing cancer cells in a patient comprising administering an antibody produced by the hybridoma PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629 or an antibody that competes with said antibodies for binding to Lng105; the invention of Group IV recites a method of detecting cells expressing Lng105 in a sample comprising contacting the sample with an antibody produced by the hybridoma PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629, or an antibody that competes with said antibodies for binding to Lng105, determining the level of binding or internalization of the antibody wherein binding or internalization of the antibody indicate expression of Lng105; The invention of Group V recites a screening method for antibodies that bind to an epitope bound by an antibody produced by the hybridoma PTA-

5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629 comprising combining a Lng105-containing sample with a test antibody and an antibody produced by the hybridoma PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629, determining the level of antibody determining the level of antibody binding and comparing the level to a control mixture, wherein the level of antibody binding of the antibody produced by the hybridoma PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629 to Lng105 in the mixture as compared to the control is indicative of the test antibody's binding to the same epitope that is bound by the antibody produced by the hybridoma PTA-5878, PTA-5879, PTA-6146, PTA-6147 or PTA-6629. The examination of each group would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups III-V are separate and distinct in having different method objectives, method steps, parameters and in the reagents used and different endpoints and are patentably distinct.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group I can be used in a materially different method such as to immunopurify the antigen in addition to the materially different therapeutic and diagnostic methods of Groups III and IV, respectively.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643